## **REMARKS**

Claims 38-78 are pending in the present application. Claims 38, 68-71 and 76 have been amended. Claims 1-37 were canceled by a previous amendment. Claims 38 and 76 are independent. Reconsideration of this application, as amended, is respectfully requested.

## **Objection to the Claims**

Claims 38, 68-71 and 76 stand objected to because of several minor informalities. As the Examiner will note, these claims have been carefully reviewed and revised, taking into consideration the specific deficiencies pointed out by the Examiner. Applicants respectfully submit that claims 38, 68-71 and 76 are now in proper form. Accordingly, reconsideration and withdrawal of the claim objection are respectfully requested.

## Rejection Under 35 U.S.C. § 112

Claim 68 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

As the Examiner will note, claim 68 has been amended to provided proper antecedent basis for the recitation "the body of the collar section." In view of this amendment, Applicants submit that claim 68 is now definite and clear. Reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 112, second paragraph are therefore respectfully requested.

## Rejections Under 35 U.S.C. §§ 102 and 103

Claims 38, 39, 55-61, 63, 67, 73 and 75-78 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rambert et al., GB 2 033 755. Claims 38-42, 44-67 and 73-78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Albrektsson et al., WO 93/16663 in view of Fontenot, U.S. Patent No. 5,639,237 and Hansson et al., U.S. Patent No. 5,588,838. These rejections are respectfully traversed.

The present invention is directed to a femur fixture for a hip-joint prosthesis. Independent claim 38 recites a combination of elements including "an intraosseous anchoring structure" and "a collar section." In addition, independent claim 38 recites "the intraosseous anchoring structure being formed form a single, one-piece member," "the screw thread profile extending from said frusto-conical proximal section towards the distal end, said frusto-conical proximal section being shorter than said proximal cylindrical section," and "said collar section extending generally radially outwardly from the intraosseous anchoring structure."

With regard to independent claim 76, this claim is also directed to a femur fixture for a hip-joint prosthesis, wherein a combination of elements are recited including "a tapered mounting section, said tapered mounting section extending from a proximal end of said collar section to a proximal end of the femur fixture." Applicants respectfully submit that the references relied on by the Examiner fail to teach or suggest the present invention as recited in the independent claims.

With regard to the Rambert et al. reference relied on by the Examiner, this reference describes a hip-joint prosthesis. The prosthesis comprises a threaded rod 7 and a recall screw 15. The Examiner considers the threaded rod 7 and the recall screw 15 to be the frusto-conical

proximal section and the proximal cylindrical section, respectively, of the presently claimed invention. However, as can be clearly understood from the figure of Rambert et al., the threaded rod 7 and the recall screw 15 are formed from two separate elements that are in threaded engagement with each other. In view of this, Rambert et al. fails to disclose "the intraosseous anchoring structure being formed from a single, one-piece member as recited in independent claim 38 of the present invention.

At page 4 of the Examiner's Office Action, the Examiner takes the position that the Rambert et al. fixture is a single, one-piece member when assembled. Applicants submit that the Examiner's position is unreasonable. Independent claim 38 clearly states that the intraosseous anchoring structure is "formed from a single, one-piece member." Referring to Figs. 3 and 4 of the present invention, it can be clearly understood that the intraosseous anchoring structure of the present invention is a single, one-piece member. However, upon a review of the figure of Rambert et al., the intraosseous anchoring structure is clearly formed by at least three different members. The fact that the three members are threaded together may be sufficient to disclose a single member; however, combining multiple pieces together would be insufficient to disclose a "one-piece" member as recited in independent claim 38.

It is believed that the Examiner is relying on the rationale that multiple elements connected together would form an "integral" structure. However, claim 38 does not recite an integral structure, it recites a "single, one-piece member." Since the Rambert et al. reference does not disclose an intraosseous anchoring structure formed from a single, one-piece member, Applicants respectfully submit that the Rambert et al. reference fails to anticipate independent claim 38 of the present invention.

With regard to independent claim 76 of the present invention, as mentioned above, this claim recites "a tapered mounting section, said tapered mounting section extending from a proximal end of said collar section to a proximal end of the femur fixture." Referring to the figure of Ramber et al., there is no tapered mounting section and therefore the Rambert et al. reference also fails to anticipate independent claim 76 of the present invention for at least this reason.

With regard to the Examiner's reliance on the Albrektsson et al. reference, Applicant respectfully submit that the Examiner's reliance on the Hansson et al. and Fontenot references is misplaced. Specifically, each of the Hanssoon et al. and Fontenot references are directed to a dental prosthesis and not to a femur fixture as in the present invention and the Albrektsson et al. reference. Applicants submit that one having ordinary skill in the art would not look to dental implants in order to solve any problem with a femur fixture and therefore the Hansson et al. and Fontenot references are non-analogous prior art to the Albrektsson et al. invention. Applicants will explain this position below.

Referring to the Albrektsson et al. reference, this reference discloses a cylindrical part 2 having a diameter that is greater than the diameter of a cylindrical part 1. The Examiner recognizes that Albrektsson et al. fails to disclose a frusto-conical proximal section at the proximal end as recited in independent claims 38 and 76. However, the Examiner relies on the Hansson et al. and Fontenot references in order to modify Albrektsson et al. to include a frusto-conical proximal section. Applicants respectfully submit that Hansson et al. and Fontenot are directed to non-analogous prior art. Specifically, one having ordinary skill in the art would not

look to dental implants to solve any problem in a femur fixture, the reason being that the problems associated with femur fixtures and dental implants are completely unrelated.

Specifically, a hip-joint fixture is located axially in a tube/pipe consisting of bone, while a dental implant fixture is located perpendicular to the longitudinal axis of the bone. Thus, the mechanics/bone situation is completely different. Furthermore, the blood supply to the bone is very different in the hip than in the jaw, and therefore questions about how the bone will be supplied (with blood) when the implant is in situ also complicates the issue. Furthermore, the load situation in the hip is very different from that in the mouth, i.e., the applied force can move through an envelope of 160° in one axis and 60° perpendicular to that. This is of course very different from the applied force on a dental implant fixture in situ. For these reasons, Applicants submit that the dental implants of Hansson et al. and Fontenot are non-analogous prior art.

With specific regard to the Examiner's reliance on the Fontenot reference, this reference discloses a frusto-conical proximal section adjacent the neck portion 14. However, Applicants submit that the Examiner's rationale in the Office Action to modify Albrektsson et al. is misplaced. The Examiner indicates that Fontenot suggests the modification "to resist displacement of the fixture, to withstand stress loads, and to increase the load bearing capacity of the fixture." However, this rationale does not appear in the Fontenot reference. The Fontenot reference is silent with regard to why the frusto-conical proximal section is provided in the Fontenot dental implant. At the very most, Fontenot would disclose the addition of an HA coating to provide such advantages. Since the Fontenot reference does not provide any advantage of providing the frusto-conical proximal section to the Albrektsson et al. reference, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness.

With regard to the Hansson et al. reference, the Examiner states that it would be obvious to modify Albrektsson et al. in view of this reference "in order to transmit the axial loads on the fixture in a bio-mechanically correct way in such a way that the bone tissue is stressed correctly around the frusto-conical part." However, referring to column 2, line 60 through column 3, line 2 of Hansson et al. (the portion relied on by the Examiner), it is the individual projections of the micro-roughness and not the frusto-conical part which provides the advantages mentioned by the Examiner as being disclosed by Hansson et al. In view of this, although it may be obvious to modify the Albrektsson et al. hip-joint prosthesis to include the mircro beads of Hansson et al., Applicants submit that Hansson et al. does not provide any suggestion to modify Albrektsson et al. to include the frusto-conical part as asserted by the Examiner. In view of this, the Examiner has also failed to establish a *prima facie* case of obviousness.

In addition, it should also be noted that none of the Albrektsson et al.. Fontenot and Hansson et al. references teach or suggest a frusto-conical proximal section and proximal cylindrical section that is "dimensioned so as to bear against the cortex of the femur neck when the intraosseous anchoring structure is in the anchored position" as recited in independent claims 38 and 76.

Referring to Fig. 1 of Albrektsson et al., the cylindrical part 2 does not bear against the cortex of the femur neck. In addition, the Hansson et al. and Fontenot references fail to disclose this aspect of the present invention, since both of these references are directed to dental implants and not femur fixtures as in the presently claimed invention and the Albrektsson et al. reference.

To the extent the Examiner takes the position that the Albrektsson et al. prosthesis would bear against the cortex of the femur neck if the prosthesis were mounted in a smaller hip joint, Applicants submit that such an argument would be without merit. It is clear from Albrektsson et

al. that the cylindrical portion should be mounted in the manner illustrated in Fig. 5, which

clearly illustrates only a portion of the cylindrical part 2 bearing against the cortex of the femur

neck. Presumably, this would be the portion that the Examiner considers to be the frusto-conical

proximal section, once the Albrektsson et al. prosthesis is modified in view of either Hansson et

al. or Fontenot. In any event, there is certainly no teaching of the proximal cylindrical section

bearing against the cortex of the femur neck as recited in the independent claims of the present

invention. In view of this, the Examiner's rejection under 35 U.S.C. § 103 is improper for this

additional reason.

With regard to dependent claims 39-42, 44-75, 77 and 78, Applicants respectfully submit

that these claims are allowable due to their respective dependence upon allowable independent

claims 38 and 76, as well as due to the additional recitations in these claims.

In view of the above amendments and remarks, Applicants respectfully submit that

claims 38-42 and 44-78 clearly define the present invention over the references relied on by the

Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejections under 35

U.S.C. §§ 102 and 103 are respectfully requested.

Allowable Subject Matter

Claim 43 has been indicated by the Examiner as being allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

Applicants greatly appreciate indication of allowable subject matter by the Examiner. However,

for the above reasons, it is believed that independent claim 38 defines the present invention over

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the references relied on by the Examiner. Accordingly, claim 43 has not been rewritten in

independent form at this time.

**CONCLUSION** 

All the stated grounds of rejection have been properly traversed and/or rendered moot.

Applicants therefore respectfully request that the Examiner reconsider all presently pending

rejections and that they be withdrawn.

It is believed that a full and complete response has been made to the Office Action, and

that as such, the Examiner is respectfully requested to send the application to Issue.

In the event there are any matters remaining in this application, the Examiner is invited to

contact Paul C. Lewis, Registration No. 43,368 at (703) 205-8000 in the Washington, D.C. area.

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Respectfully submitted,

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